National Fish Meal and Oil Association

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CITIZEN PETITION

The undersigned submits this petition under 21 CFR parts 10.20 and 10.30 of the Federal Food, Drug and Cosmetic Act to request the Commissioner of Food & Drugs to amend 21 CRF part 184.1472 *Hydrogenated and Partially Hydrogenated Menhaden Oils* by areallocation of the uses ofmenhaden oil as presently established in part 184.1472 and keeping the total estimated usage at a level not exceeding 3g/per day of EPA and DHA, consistent with 21 CRF 184.1(b)(2) based on the FDA determination that the total usages level of 3g/per day is GRAS (Reference Section IV(4) and Table 1 of this Citizen Petition).

I. INTRODUCTION

The final rule affirming that menhaden oil is generally recognized as safe (GRAS) as a direct human food ingredient with specific limitations was published in the *Federal Register* on June 5, 1997 (62 FR 3075 1). This affirmation was in response to a petition (GRASP 6G0316) submitted by the National Fish Meal and Oil Association (NFMOA). The NFMOA petition included information about the identity of, and manufacturing processes for, menhaden oil and the results of an extensive search of the published scientific literature with respect to the safety of fish oils in general.

The current regulation for menhaden oil (2 1 CFR 184.1472) provides that menhaden oil may be used in foods only within specific limitations such that the average exposure to two fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), does not exceed 3 grams/person/day (g/p/d) for the two fatty acids combined. Table 1 lists the food categories and maximum levels of use of menhaden oil in the foods covered under 2 1 CFR 184.1472.

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The operative specific limitation for menhaden oil is the 3 g/p/d ceiling on consumption of the two fatty acids, EPA and DHA. The currently approved food categories and maximum levels of use of menhaden oil were proposed by NFMOA to meet that limitation, but have no other importance. The Food and Drug Administration (FDA) conducted no independent evaluation of the categories and levels beyond determining that the net consumption of EPA+DHA from the proposed uses would not exceed 3 g/p/d. Consequently, a reallocation of the uses of menhaden oil, keeping the total estimated usage at a level not exceeding 3 g/p/d of EPA+DHA, is consistent with 21 CFR 184.1 (b)(2) and is GRAS based on the FDA determination that the total usage level of 3 g/p/d is GRAS.

II. IDENTITY OF THE SUBSTANCE

A. Common or usual name:

Menhaden Oil

B. Source information and quantitative composition

Menhaden oil as referred to in this dossier is identical to the substance that is affirmed as GRAS by FDA (21 CFR 184.1472).

Menhaden oil is a refined marine oil that is derived from menhaden fish (Brevoortia species). It consists primarily of triglycerides, with small amounts of monoglycerides and diglycerides. The triglycerides are esters of glycerol and fatty acids with chains of 14 to 22 carbon atoms. Menhaden oil differs from edible vegetable oils and animal fats in its high proportion of polyunsaturated fatty acids with 4, 5, and 6 double bonds (about 25% by weight). The mean percentages by weight for these polyunsaturated fatty acids in menhaden oil are C18:4 (2.3%); C20:4 (2.0%); C20:5, eicosapentaenoic acid or EPA (13.1%); C22:5 (2.5%); and C22:6, docosahexaenoic acid or DHA (6.7%). Menhaden oil also contains about 33% saturated fatty acids and about 3 1% monounsaturated fatty acids. EPA and DHA, together comprising 19.8% by weight of menhaden oil, are the major sources of omega-3 fatty acids from fish oil.

C. Method of Manufacture

As described in 2 1 CFR 184.1472, menhaden oil is prepared by cooking and pressing the source fish. The resulting crude oil is then refined using the following steps:

- Storage (winterization)
- Degumming (optional)
- Neutralization

- Bleaching
- Deodorization

D. Characteristic Properties and Final Product Specifications

Menhaden oil meets the following specifications listed in 21 CFR 184.1472:

- Color and state: yellow liquid to white solid
- Odor: odorless to slightly fishy
- Saponification value: between 180 and 200 as determined by the American Oil Chemists' Society (AOCS) Official Method Cd 3-25—"Saponification Value"
- Iodine number: not less than 120 as determined by the AOCS Recommended Practice Cd 1d-92—"Iodine Value of Fats and Oils, Cyclohexane-Acetic Acid Method"
- Unsaponifiable matter: not more than 1.5 percent as determined by the AOCS Official Method Ca 6b-53—"Unsaponifiable Matter"
- Free fatty acids: not more than 0.1 percent as determined by the AOCS Official Method Ca 5a-40—"Free Fatty Acids"
- Peroxide value: not more than 4 mEq/kg oil as determined by the AOCS Official Method Cd 8-53—"Peroxide Value, Acetic Acid-Chloroform Method" or Recommended Practice Cd 8b-90—"Peroxide Value, Acetic Acid-Isooctane Method"
- Lead: not more than 0.1 mg/kg oil as determined by the AOCS Official Method Ca 18c-91—"Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrometry"
- Mercury: not more than 0.5 mg/kg oil as determined by the method entitled "Biomedical Test Materials Program: Analytical Methods for the Quality Assurance of Fish Oil," published in the "NOAA Technical Memorandum NMFS-SEFC-211," F.M. Van Dolah and S.B. Galloway, editors, National Marine Fisheries Service, U.S. Department of Commerce, pages 71-88, November 1988

III. INTENDED USE OF MENHADEN OIL

A. Existing and Proposed Food Uses and Use Levels of Menhaden Oil

The foods in which menhaden oil is currently approved for use along with proposed reductions in use levels and proposed additional food categories/use levels are shown in Table 1. The number in parenthesis following the name of each food category is the paragraph listing that food category in 21 CFR 170.3(n).

B. Functionality (Technical Effect)

Menhaden oil will be used as a source of fat in foods. Menhaden oil may also be added to foods for its nutritional properties.

IV. SAFETY OF MENHADEN OIL AT PROPOSED LEVEL OF EXPOSURE

A. FDA Affirmation of General Recognition of Safety

The Food and Drug Administration (FDA) affirmed the GRAS status of menhaden oil in its 1997 Final Rule. The agency stated that, "the use of menhaden oil as a direct food ingredient is safe, provided that daily intakes of EPA and DHA from menhaden oil do not exceed 3 g/p/d" (62 FR 30754)."

Prior to affirming the GRAS status of menhaden oil, FDA reviewed all of the data submitted to the agency in the NFMOA petition (GRASP 6G03 16). The agency also contracted with the Mitre Corporation to perform an independent analysis of the scientific literature on the safety of menhaden oil. The Mitre report, "Health Effects of Refined Menhaden Oil," was issued in April, 1989, and is available from the National Technical Information Service (Order No. PB89-182398).

The report reviewed the following issues regarding human food use of menhaden oil:

- History of use of menhaden oil and related products;
- Biochemistry of polyunsaturated fatty acids;
- Effects of the ingestion of menhaden oil, other fish oils, and related omega-3 fatty acids including the following:
  - Absorption and distribution (animal and human studies);
  - Biochemical effects (effects on prostaglandin and leukotriene synthesis, effect on membrane fluidity, effects on fatty acid oxidation and desaturation, effects on enzyme induction);
  - Effects on hemostasis (epidemiological and clinical studies);
  - Effects on serum lipids (animal and human studies);
  - Immunological effects (animal and human studies);
  - Carcinogenicity;
  - Reproductive effects (animal and human studies);
  - Retinal and visual effects;
  - Neurological effects;
  - Cardiac lipidosis and related cardiotoxic effects;
  - Other effects such as gastrointestinal disturbance and cardiac stress tolerance;

- Toxicity of oxidized or heated fish oils.

This report concluded that among potential adverse effects evaluated, an "increase in bleeding time is the only prominent health effect observed in humans that has been firmly established as a consequence of fish oil ingestion" (p. 7-l). The report further stated that, "The magnitude of the effect at this low dose [3 g/p/d of omega-3 fatty acids] is not a cause for alarm, but a lack of systematic dose-response data precludes prediction of the severity of the effect at higher daily intakes" (p.7-2).

FDA estimated that the mean exposure to EPA and DHA from the use of menhaden oil at the "most probable use levels" (90% of the maximum use levels) proposed for the various food categories included in the petition would be 2.8 g/p/d (FDA memorandum from Michael DiNovi to Lawrence Lin, October 19, 1993).

Based on the findings of the Mitre safety review and FDA's determination that the estimated mean exposure to EPA and DHA from the petitioned uses of menhaden oil would be less than 3 g/p/d, FDA concluded that, "FDA has further determined that the many pertinent published human clinical studies provide an adequate basis to conclude that the safety of the petitioned uses of menhaden oil is generally recognized among the community of experts qualified by scientific training and experience to evaluate the safety of food ingredients. Therefore, the agency is affirming that the use of menhaden oil as a direct human food ingredient is GRAS with specific limitations" (62 FR 30754)."

B. Exposure Analysis: Estimated Daily Intake (EDI) of Product

As noted above, 21 CFR 184.1472 includes a list of specific limitations that were proposed by NFMOA to meet FDA's requirement that the mean exposure to EPA+DHA from menhaden oil not exceed 3 g/p/d. The proposed amended list of specific limitations for the use of menhaden oil includes two classes of changes:

- The maximum level of use of menhaden oil in some currently approved food categories is reduced, and
- The list includes additional food categories along with maximum levels of use in these new categories.

The net effect of these proposed changes is an estimated exposure to EPA+DHA from the proposed amended list of specific limitations for the use of menhaden oil that does not exceed the exposure of 3 g/p/d regarded by FDA as GRAS.

1. Methods of Estimating Exposure to EPA+DHA

As in the original petition and FDA's exposure estimates, EPA+DHA are assumed to constitute 20% by weight of menhaden oil. However, the exposure estimate in the original petition was based on food frequency data from the 1982-87 5-Year Menu Census of the Market Research Corporation of America's Food Frequency Survey, combined with standard portion sizes based on data from the USDA's 1987-88 Nationwide Food Consumption Survey (FDA, 1993). For example, the former survey provided the average number of occasions over a 14-day period that an individual consumed cookies. The latter USDA survey provided data on the average weight (in grams) of a serving of cookies. These data were combined to determine the average daily intake of cookies and therefore the average daily intake of menhaden oil contained in cookies.

FDA is now basing most of its estimates of exposure to food constituents on a more recent dataset, the USDA 1989-91 Continuing Survey of Food Intakes by Individuals (CSFII; ARS, 1994) (FDA, 1995). In order to facilitate the agency's ability to confirm the exposure estimates included in this GRAS determination, ENVIRON re-calculated the ED1 for EPA+DHA under the current specific limitations using data from the 1989-91 CSFII. This estimate was then compared to the calculated ED1 using the proposed amended specific limitations in order to determine the effect of the changes.

In its estimate of exposure to EPA+DHA (FDA, 1993), FDA analyzed the 2+ years old age group. Further, FDA noted that, "Because of the wide variety of food types included in the analysis, the total sample and eaters-only populations are equivalent." The "Eaters-only" population is defined as the individuals in the survey who consumed at least one of the analyzed foods over the survey period. The "total sample" population is defined as all individuals who participated in the survey. The foods in the original menhaden oil GRAS petition included foods such as breads, fat and oils, cereals, snack foods, and eggs that are commonly consumed by most individuals. Because nearly everyone in the "total sample" survey population consumed at least one of these foods during the survey period, the "total sample" population is essentially the same as the "eaters-only" population.
Consequently, FDA estimated total mean exposure to EPA+DHA by adding the per-capita ("total sample") mean exposures from each proposed food category.

FDA calculated the maximum potential exposure as well as a "most probable use level" exposure estimate. For the maximum potential exposure, FDA assumed that menhaden oil was used in foods at 100% of the petitioned use level. For the most probable use level, FDA assumed that menhaden oil would only be used in foods at 90% of the petitioned use level. It was FDA's belief that the exposure estimate based on "most probable use level" is more representative of likely actual exposure to menhaden oil by the population (FDA, 1993). The assumption that menhaden oil would be added to all of the petitioned foods at 90% of the petitioned use level is still a highly conservative estimate of likely consumer exposure.

For all exposure estimates contained in this document, ENVIRON followed FDA's procedures by determining per capita exposures for the population of individuals 2+ years of age. ENVIRON determined the estimated mean daily exposure of the population to menhaden oil at the 90% "most probable use level." By following FDA's procedures, ENVIRON assured that the basis on which FDA affirmed the GRAS status of menhaden oil would remain unchanged. In addition, however, we calculated potential mean daily exposure at the "worst case" 100% use level to assure that it would not exceed 3 g/p/d.

2. Food Consumption Survey

The 1989-91 CSFII was a three-year survey in which data were collected from a stratified area probability sample of individuals residing in households in the U.S. Households represented a cross-section of the population of the 48 conterminous states and the District of Columbia. The 1989-91 CSFII obtained individual food consumption data for three consecutive days. The first day of individual intake was collected by trained interviewers using a 24-hour recall of foods and beverages consumed the previous day. Intakes for the other two days were based upon records maintained by the respondent for the day of the interview and the following day. Although about 80% of individuals reported consumption for all three days of the survey, some individuals reported consumption for only one or two days. Only data from individuals who supplied information on dietary intake for all three days were used in these analyses.

The 1989-91 CSFII was not designed to be self-weighting. Weights were developed by USDA to adjust for over- and under-representation of certain population subgroups in the unweighted sample due to the sample design (low-income households were oversampled), non-response, and unequal interviewing across seasons and days of the week.

Individuals were surveyed in all four seasons and on all days of the week. In addition to information on food consumption, the survey collected physiological and demographic data such as sex, age, self-reported height and weight, ethnic group, pregnancy and lactation status, household income, and urbanization category of the household. This information permits assessment of food consumption by specific population groups of interest.

Food intake was recorded by time of day and by eating occasion (breakfast, brunch, lunch, dinner, supper, and snack) as defined by the respondent. Separate entries were made in the survey database for each food consumed according to a system developed by USDA. There are approximately 6,000 separate 7-digit food codes in the database, representing nine major food groups. Quantities of foods and beverages consumed were recorded as reported, in household measures, weights, dimensions, or common units (e.g., slice, piece). All quantities were converted to grams by USDA.

The survey also identified the source of food, i.e., eaten at home, taken from home and eaten away from home, or never brought into the home. When foods were obtained and eaten away from home, the location was specified as restaurant, cafeteria, school, day-care center, community feeding program, vending machine, store, or someone else's home. Foods obtained from fast-food restaurants were identified as eaten at home or away from home.

A total of 11,488 individuals age 2 and older provided three full days of food consumption data and were included in the analyses.

3. Currently Approved Uses of Menhaden Oil

The following currently approved uses of refined menhaden oil were included in the exposure estimates; the number in parenthesis following the name of each food is the paragraph listing that food in 2 1 CFR 170.3(n). For each category of food, the USDA food codes included in the analyses are briefly discussed.

- Cookies (1): includes all types of cookies, both regular and dietetic.
- Crackers (1): includes sweet and non-sweet crackers, regular and low sodium.
- Breads and rolls, white and dark (1). Includes all yeast breads, rolls, muffins, bagels, and croissants reported separately as well as the bread component of sandwiches reported as mixtures such as cheeseburgers, frankfurters, egg-muffin sandwiches, and toasted cheese sandwiches.
- Pies (1): includes all pies and tarts, both fruit and custard.
- Cakes (1): includes all cakes, cupcakes, shortcakes, cobblers, eclairs, turnovers, granola bars, Danishes, doughnuts, coffee cakes, and other sweet pastries.
- Cereals (4): includes all cereals, both ready-to-eat and cooked.
- Cheese products (5): includes all processed cheeses and cheese spreads, cheese mixtures, and imitation cheeses.
- Condiments (8): includes condiments such as catsup and mustard reported separately as well as the condiment component of foods reported as mixtures such as hamburgers and frankfurters.
- Egg products (11): includes all egg dishes such as scrambled eggs and omelets, egg soups, and all egg substitutes as well as the egg component of egg based sandwiches and frozen meals.
- Fats and oils (12): includes butter, margarine, and other table spreads, cooking fats, and both regular and low-calorie salad dressings.
- Fish products (13): includes all restructured seafood and all canned seafood packed in oil.

- Frozen dairy desserts (20): includes all milk based frozen desserts such as ice cream (and ice cream mixtures such as sundaes and ice cream bars), ice milk, and dietary frozen milk desserts.
- Gravies and sauces (24): includes gravies and sauces such as milk based sauces, tomato based sauces, legume based sauces, sweet sauces, and meat and poultry based gravies reported separately as well as the sauce or gravy component of foods reported as mixtures such as barbecued ribs or frozen meals.
- Meat products (29): includes chipped beef and beef bacon as well as sausages, luncheon meats, canned processed meats, and meat based spreads.
- Yogurt (3 1): includes all plain, fruit, and frozen yogurts.
- Nut products (32): includes peanut butter as well as spreads and sauces based on peanuts or other nuts.
- Snack foods (37): includes potato chips and sticks, corn and tortilla chips, and pretzels.
- Soups and soup mixes (40): includes all soups such as condensed and made from mixes reported separately as well as the soup component of foods reported as mixtures such as casseroles based on mushroom soup.

4. Proposed Additional Uses of Menhaden Oil

- Quick breads (1): includes biscuits, muffins, scones, cornbread, tortillas, and fruit breads,
- Non-alcoholic beverages (3): includes all soft drinks and all noncarbonated beverages made from dry mixes.
- Chewing gum (6): includes both regular and dietetic chewing gums.
- Confections and frostings (9): includes icings and fillings reported separately (those reported as components of cakes and other baked goods are included with the food as reported); also includes sugars other than white granulated sugar reported separately.
- Dairy product analogs (10): includes cream substitutes and nondairy whipped toppings.
- Nondairy milk (10): includes all fluid imitation milks.
- Gelatins and puddings (22): includes puddings, custards, and gelatin desserts reported separately and the gelatin component of foods reported as mixtures such as fruit salads
- Pasta (23): includes pasta reported separately as well as the pasta component of foods reported as mixtures such as spaghetti, lasagna, and macaroni and cheese.
- Hard candy (25): includes both regular and dietetic hard candies.
- Jams and jellies (28): includes all jams, jellies, marmalades, and preserves, both regular and 'dietetic.
- Gelatin based drinks and meal supplements (29): includes all gelatin beverages and meal supplements/replacements.

- Flavored milk and milk drinks (3 1): includes chocolate and other flavored milks, cocoa, malted milk, milk shakes, eggnog, and other milk drinks.
- Milk products (3 1): includes evaporated and condensed milks, sweet creams, and sour cream and dips based on sour cream.
- Milk based meal replacements (31): includes instant breakfast, milk based diet beverages, and supplement and meal replacement beverages.
- Milk dry and powdered mixtures (31): includes all dry and powdered milk based beverages and non-reconstituted supplements and meal replacement products.
- Plant protein products (33): includes all soy or other vegetable derived meat substitutes, supplements, protein bars, and meal replacements.
- Poultry products (34): includes processed chicken and turkey products such as chicken roll and canned turkey.
- Processed fruit drinks (35): includes all fruit drinks, ades, and punches.
- Processed vegetable drinks (36): includes tomato juice and other vegetable based beverages.
- Soft candy (38): includes both regular and dietetic soft candies.
- Sugar, white granulated (4 1): includes granulated white sugar reported separately.
- Sugar substitutes (42): includes all sugar substitutes reported separately.
- Sweet sauces, toppings, and syrups (43): includes all syrups, honey, molasses, and sweet toppings reported separately (those reported as components of ice cream dishes and other frozen desserts are included with the food as reported).

5. Current and Proposed Maximum Levels of Use of Menhaden Oil

The proposed changes to the specific limitations of allowable uses for menhaden oil include reductions in the maximum levels of use of menhaden oil in some currently approved food categories as well as the inclusion of new food categories. Table 1 shows the current and proposed maximum levels of use of menhaden oil in both currently approved and proposed new categories of food.

6. Intake of EPA+DHA From Current Uses of Menhaden Oil

The estimated mean per capita daily intake of EPA+DHA from the current regulated uses of menhaden oil is 2762 mg/p/d at the 100% maximum use level and 2486 mg/p/d at the 90% most probable use level (Table 2).

7. Intake of EPA+DHA From Adjusted Current Uses of Menhaden Oil

The category for cakes, cobblers, and danish was reduced from 10% menhaden oil to 4% menhaden oil. The category for pies was reduced from 7% to 3% menhaden oil. The category for edible fats and oils was reduced from 20% to 12% menhaden oil and the category for fish products was reduced

from 20% to 5% menhaden oil. The category for meat products was reduced from 10% to 5% menhaden oil. By lowering the use levels of menhaden oil in these food categories, the estimated mean per capita intake of EPA+DHA at the 100% use level was reduced from 2762 mg/p/d (Table 2) to 2 143 mg/day (Table 3). At the 90% use level, the intake of EPA+DHA was reduced from 2486 mg/p/d (Table 2) to 1929 mg/p/d (Table 3).

8. Intake of EPA+DHA From Proposed Additional Uses of Menhaden Oil

The mean per capita estimated daily intake of EPA+DHA from the proposed additional uses of menhaden oil is 857 mg/person (Table 4) at the 100% use level. At the 90% use level, the mean per capita estimated daily intake of EPA+DHA from the proposed additional uses of menhaden oil is 77 1 mg/p/d (Table 4). The largest contributors to the ED1 from proposed additional uses are non-alcoholic beverages (247 mg/p/d), pasta (164 mg/p/d), and quick breads (99 mg/p/d).

9. Total Intake From Adjusted Current Uses Plus Additional Proposed Uses

The estimated mean daily intake of EPA+DHA from the adjusted current uses and the proposed additional uses is 3000 mg/p/d at the maximum use level (100%) of menhaden oil (Table 5). At the 90% "most probable use level," the estimated mean daily exposure of EPA+DHA is 2700 g/p/d (Table 5).

V. BASIS FOR GRAS DETERMINATION

FDA has affirmed that menhaden oil is generally recognized as safe at a level of intake that results in a mean daily exposure to EPA+DHA up to 3 g/p/d (FDA, 1997). The exposure analysis described above demonstrates that the estimated mean daily exposure of the U.S. population to EPA and DHA from the proposed new food uses combined with the revised existing uses does not exceed 3 g/p/d. This is true even if it is assumed that menhaden oil will be used at 100% of the maximum use levels in all approved foods, a more conservative assumption than that made by FDA in its GRAS affirmation. Therefore, we conclude that menhaden oil is generally recognized as safe for the uses and use levels proposed.

REFERENCES

Agricultural Research Service (ARS) (1994). Continuing Survey of Food Intakes by Individuals 1989-91. U.S. Department of Agriculture. Computer Tapes.

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Food and Drug Administration (1995). Estimating Exposures to Direct Food Additives and Chemical Contaminants, Office of Premarket Approval.

Mitre Corp. (1989). Health Effects of Refined Menhaden Oil. (National Technical Information Service, Order No. PB89-182398).

National Fish Meal and Oil Association (1986). Petition to FDA for Affirmation That Menhaden Oil and Partially Hydrogenated Menhaden Oil are GRAS for Use as Direct Human Food Ingredients (GRASP 6G03 16).

VI. ENVIRONMENTAL IMPACT

Actions under this Citizen Petition to amend 21 CRF 184.1472 will not result in the production or distribution of any substance into the environment. 29 CFP part 25.24 (8), (9), (12)(b)(7).

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition.

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Table 1. Current and Proposed Maximum Levels of Use of Menhaden Oil

Category of Food	Current Maximum Level of Use In Food As Served	Proposed Maximum Level of Use In Food As Served
Cookies, crackers (1)	5.0%	5.0%
Breads and rolls (1)	1.0%	1.0%
Pies (1)	7.0%	3.0%
Cakes (1)	10.0%	4.0%
Cereals (4)	4.0%	4.0%
Cheese products (5)	5.0%	5.0%
Condiments (8)	5.0%	5.0%
Egg products (11)	5.0%	5.0%
Fats and oils (12)	20.0%	12.0%
Fish products (13)	20.0%	5.0%
Frozen dairy desserts (20)	5.0%	5.0%
Gravies and sauces (24)	5.0%	5.0%
Meat products (29)	10.0%	5.0%
Yogurt (3 1)	4.0%	4.0%
Nut products (32)	5.0%	5.0%
Snack foods (37)	5.0%	5.0%
Soups and soup mixes (40)	3.0%	3.0%
Quick breads (1)	--	4.0%
Non-alcoholic beverages (3)	--	0.5%
Chewing gum (6)	--	3.0%
Confections and frostings (9)	--	5.0%
Dairy product analogs (10)	--	5.0%
Nondairy milk (10)	--	1.0%
Gelatins and puddings (22)	--	1.0%
Pasta (23)	--	2.0%
Hard candy (25)	--	10.0%
Jams and jellies (28)	--	7.0%
Gelatin based drinks and meal supplements (29)	--	10.0%
Flavored milk and milk drinks (3 1)		0.5%
Milk products (3 1)	--	5.0%
Milk based meal replacements (3 1)	--	1.0%
Milk dry and powdered mixtures (3 1)		3.0%
Plant protein products (33)	--	5.0%
Poultry products (34)	--	3.0%
Processed fruit drinks (35)	--	1.0%
Processed vegetable drinks (36)	--	1.0%
Soft candy (38)	--	4.0%
White granulated sugar (41)	--	4.0%
Sugar substitutes (42)	--	10.0%
Sweet sauces, toppings, and syrups (43)	--	5.0%

Table 2. Estimated Mean Daily Intake of Menhaden Oil (MO) and EPA+DHA From the Addition of Menhaden Oil to Foods Included in the Current Menhaden Oil GRAS Regulation (21 CFR 184.1472).

Food Category	%MO	Oil or Fatty Acids	Mean Per Capital Intake (mg) 100% Use Level	90% Use Level
Breads	1	MO	605.2	544.7
		EPA+DHA	121.0	108.9
Crackers	5	MO	168.2	151.4
		EPA+DHA	33.6	30.2
Cookies	5	MO	360.2	324.2
		EPA+DHA	72.0	64.8
Cakes, cobblers, danish	10	MO	1494.7	1345.2
		EPA+DHA	298.9	269.0
Pies	7	MO	413.3	372.0
		EPA+DHA	82.7	74.4
Cereals, hot/cold and RTE	4	MO	1357.5	1221.8
		EPA+DHA	271.5	244.4
Snack Foods	5	MO	295.0	265.5
		EPA+DHA	59.0	53.1
Condiments	5	MO	129.0	116.1
		EPA+DHA	25.8	23.2
Gravies and sauces	5	MO	1225.9	1103.3
		EPA+DHA	245.2	220.7
Fats and Oils	20	MO	2706.6	2435.9
		EPA+DHA	541.3	487.2
Yogurt	4	MO	305.0	274.5
		EPA+DHA	61.0	54.9
Cheese products	4	MO	247.1	222.4
		EPA+DHA	49.4	44.5
Frozen Dairy Products	5	MO	759.2	683.3
		EPA+DHA	151.8	136.6
Fish products	20	MO	31.1	28.0
		EPA+DHA	6.2	5.6
Soups and Soup Mixes	3	MO	1398.4	1258.6
		EPA+DHA	279.7	251.7
Meat products/luncheon meats	10	MO	1747.7	1572.9
		EPA+DHA	349.5	3 14.6
Eggs	5	MO	460.2	414.2
		EPA+DHA	92.0	82.8
Nut Products	5	MO	106.3	95.7
		EPA+DHA	21.3	19.2
Total			2762.2	2486.0

Source: USDA CSFII 1989-1991 three-day intakes; weighted data.

Table 3. Estimated Mean Daily Intake of Menhaden Oil (MO) and EPA+DHA From the Addition of Menhaden Oil to Foods at Adjusted Use Levels

Food Category	% MO	Oil or Fatty Acids	Mean Per Capital Intake (mg) 100% Use Level	90% Use Level
Breads	1	MO	605.2	544.7
		EPA+DHA	121.0	108.9
Crackers	5	MO	168.2	151.4
		EPA+DHA	33.6	30.2
Cookies	5	MO	360.2	324.2
		EPA+DHA	72.0	64.8
*Cakes, cobblers, danish	4	MO	597.9	538.1
		EPA+DHA	119.6	107.6
*Pies	3	MO	177.1	159.4
		EPA+DHA	35.4	31.9
Cereals, hot/cold and RTE	4	MO	1357.5	1221.8
		EPA+DHA	271.5	244.4
Snack Foods	5	MO	295.0	265.5
		EPA+DHA	59.0	53.1
Condiments	5	MO	129.0	116.1
		EPA+DHA	25.8	23.2
Gravies and sauces	5	MO	1225.9	1103.3
		EPA+DHA	245.2	220.7
*Fats and Oils	12	MO	1624.0	1461.6
		EPA+DHA	324.8	292.3
Yogurt	4	MO	305.0	274.5
		EPA+DHA	61.0	54.9
Cheese products	5	MO	247.1	222.4
		EPA+DHA	49.4	44.5
Frozen Dairy Products	5	MO	759.2	683.3
		EPA+DHA	151.8	136.6
*Fish products	5	MO	24.8	22.3
		EPA+DHA	5.0	4.5
Soups and Soup Mixes	3	MO	1398.4	1258.6
		EPA+DHA	279.7	251.7
*Meat products/luncheon meats	5	MO	873.9	786.5
		EPA+DHA	174.8	157.3
Eggs	5	MO	460.2	414.2
		EPA+DHA	92.0	82.8
Nut Products	5	MO	106.3	95.7
		EPA+DHA	21.3	19.2
New Total		EPA+DHA	2143.0	1928.7

Source: USDA CSFII 1989-1991 two-day intakes; weighted data.

Table 4. Estimated Mean Daily Intake of Menhaden Oil (MO) and EPA+DHA From the Addition of Menhaden Oil to Foods Not Included in the Current Menhaden Oil GRAS Regulation (21 CFR 184.1472)

Food and FDA Food Category Number	% MO	Oil or Fatty Acids	Mean Per Capital Intake (mg)	
			100% Use Level	90% Use Level
Quick Breads (1)	4	MO	497.0	447.3
		EPA+DHA	99.4	89.5
Non-alcoholic Beverages (3)	0.5	MO	1232.5	1109.3
		EPA+DHA	246.5	221.9
Gelatin Beverages/Meal Supplements	10.0	MO	5.4	4.9
		EPA+DHA	1.1	1.0
Chewing Gum (6)	3.0	MO	61.0	54.9
		EPA+DHA	12.2	11.0
Frostings and Confections (9)	5	MO	5.7	5.1
		EPA+DHA	1.1	1.0
Imitation and Soy Milk (10)	1.0	MO	1.7	1.5
		EPA+DHA	0.3	0.3
Non-Dairy Cream Substitutes (10)	5.0	MO	36.3	32.7
		EPA+DHA	7.3	6.6
Dairy Cream Subs Powdered (10)	5.0	MO	12.8	11.5
		EPA+DHA	2.6	2.3
Gelatin and puddings (22)	1.0	MO	79.8	71.8
		EPA+DHA	16.0	14.4
Pasta, all (23)	2.0	MO	819.3	737.4
		EPA+DHA	163.9	147.5
Hard Candy (25)	10	MO	25.8	23.2
		EPA+DHA	5.2	4.7
Jams and Jellies (28)	7	MO	146.0	131.4
		EPA+DHA	29.2	26.3
Milk Based Meal Replacements (3 1)	1.0	MO	11.4	10.3
		EPA+DHA	2.3	2.1
Milk dry and powdered Mixtures (3 1)	3.0	MO	23.4	21.1
		EPA+DHA	4.7	4.2
Condensed Evaporated Milk (3 1)	5.0	MO	22.9	20.6
		EPA+DHA	4.6	4.1
Flavored milk drinks (3 1)	0.5	MO	66.7	60.0
		EPA+DHA	13.3	12.0
Sweet Dairy Cream (3 1)	5.0	MO	71.4	64.3
		EPA+DHA	14.3	12.9
Sour cream (3 1)	5.0	MO	51.0	45.9
		EPA+DHA	10.2	9.2

Food and FDA Food Category Number	% MO	Oil or Fatty Acids	Mean Per Capital Intake (mg) 100% Use Level	90% Use Level
Soy Protein Powders (33)	5	MO	2.3	2.1
		EPA+DHA	0.5	0.5
Soy Protein Drinks (33)	1.0	MO	3.6	3.2
		EPA+DHA	0.7	0.6
Soy Protein Bars (33)	5.0	MO	0.2	0.2
		EPA+DHA	0.0	0.0
Soy Based Desserts (33)	5.0	MO	0.2	0.2
		EPA+DHA	0.0	0.0
Meat Substitute lunch meat (33)	5.0	MO	1.4	1.3
		EPA+DHA	0.3	0.3
Vegetable Protein Bacon Bits (33)	5.0	MO	3.6	3.2
		EPA+DHA	0.7	0.6
Vegetable Protein entree (33)	5.0	MO	0.3	0.3
		EPA+DHA	0.1	0.1
Vegetable Protein sandwich (33)	5.0	MO	2.5	2.3
		EPA+DHA	0.5	0.5
Poultry canned and ground (34)	3	MO	8.3	7.5
		EPA+DHA	1.7	1.5
Fruit Drinks (3 5)	1.0	MO	527.8	475.0
		EPA+DHA	105.6	95.0
Vegetable Juices/Drinks (36)	1.0	MO	29.6	26.6
		EPA+DHA	5.9	5.3
Soft Candy (38)	4	MO	150.2	135.2
		EPA+DHA	30.0	27.0
sugar (4 1)	4	MO	146.8	132.1
		EPA+DHA	29.4	26.5
Sugar Substitutes (42)	10	MO	13.6	12.2
		EPA+DHA	2.7	2.4
Sweet Sauces and Toppings (43)	5	MO	224.6	202.1
		EPA+DHA	44.9	40.4
TOTAL			857.0	771.3

Source: USDA CSFII 1989-1991 two-day intakes; weighted data.

Table 5. Estimated Mean Daily Per Capita Intake of EPA+DHA From Menhaden Oil Added To Foods Covered Under This GRAS Determination

	Mean Per Capita Intake EPA+DHA (mg)	
	100% Use Level	90% **Use Level**
Adjusted Current Uses	2143.0	1928.7
Proposed Additional Uses	857.0	771.3
Total	**3000.0**	2700.0

Source: USDA CSFII 1989-1991 two-day intakes; weighted data.

Appendix

Foods and Food Codes Used in the Intake Analyses

Codes For Foods Covered Under the Menhaden Oil GRAS Regulation

NFCSCODES "Breads rolls English muffins and mixtures"

275	322	419	423	51

NFCSCODES "Crackers"

541	542	543

NFCSCODES "Cookies"

532

NFCSCODES "Pies"

533

NFCSCODES "Cakes, cobblers, danish, coffee cake"

531	535	562003	56203	56207
534	536	56201		
56208	570	572	573	574
562100	571			

NFCSCODES "Snack foods ie chips and cornchips etc."

5440101	5440102	5440105	5440108	5440109
5440110	5440120	5440208	544060 1	5440620
5441211	544200 1	544300 1	544400 1	712

NFCSCODES "Condiments: catsup and mustard excluding relishes"

2751022	2751033	275 1040	275 1056	2751067
275 1023	2751034	2751043	275 1057	275 1068
275 1025	2751035	2751048	275 1059	2756034
2751026	2751036	2751051	2751061	7440101
2751028	2751037	275 1052	275 1062	7440111
2751031	2751038	275 1054	275 1063	744020 1
2751032	2751039	275 1055	275 1066	744050 1

NFCSCODES "Gravies and sauces"

1341100	2712012	2715035	2724330	2754033
1341200	27 12025	2716001	2724360	2756072
2130420	27 14600	2716010	2724370	2811011
2130421	2715011	2716201	2734397	2811022
2611916	2715014	2716205	2751070	2811023
2611918	2715019	2721110	2751072	2811025
2711105	2715020	2721119	2751302	2811031
2711141	2715021	2721210	2751306	2811033

2811035	2815301	58107	5813471	744020 1
2811037	2815401	5812615	5814610	7440225
2811050	2816031	581263 1	5814611	7440226
2811051	2816071	5813132	5814612	7440235
2811064	2850000	5813152	5814613	7440301
2811066	285000 1	5813153	5814615	7440305
2811305	2850004	5813160	5814620	744040 1
2813311	2850005	5813211	5816331	7440403
2814011	2850010	5813231	5830102	7440405
2814025	2852000	5813236	5830105	7440601
2814083	2852010	5813271	5830204	7440610
28143 17	2852200	5813280	5830205	7440650
28143 19	4120102	5813281	58303 10	7551101
2814321	4120104	5813282	5830320	8130102
2814410	4120510	5813291	5830405	8130201
2814501	4142010	5813312	5830406	8130202
28 14502	4142040	5813313	5830420	8130203
2814512	4142045	5813412	5830425	8130205
2814521	4220410	5813413	5830430	8130206
2814531	5810182	5813461	5830435	8130207
2814561	5810183	5813462	5830602	8131200
2814581	58106	5813466		

NFCSCODES "Margarine butter dressings shortenings"

811	8120320	8130205	8130207	831
8120300	8130204	8130206	8131200	832
8120310				

NFCSCODES "Yogurt"

114

NFCSCODES "Cheese products"

144 145 146

NFCSCODES "Frozen dairy products"

131

NFCSCODES "Fish products ie surimi canning oils"

2610018	2613718	2615518	2725052
2610118	2613918		

NFCSCODES "Soup mixes"

147	2722015	2731331	2741410	416
2711400	2724225	273 1332	2741420	584
2712009	2724340	2731531	2741811	718
2714400	2725063	2731532	27443 11	723
2721117	2725071	2734347	27443 12	735
2721240	2725083	2734348	274505 1	746
272 1340	2725090	2734541	2745065	756
2721342	2731161	2734542	2745066	
2722003	2731162	2735041	283	

NFCSCODES "Meat products"

216	252

NFCSCODES "Eggs and egg substitutes"

321	322	323	33	350

NFCSCODES "Nut products"

422	4230101	4230201	4230301

B. Additional Codes For Foods Covered Under this Menhaden Oil GRAS Determination

NFCSCODES "Condensed and evaporated milks"

112

NFCSCODES "Flavored milk drinks"

115

NFCSCODES "Sweet dairy cream"

12%

NFCSCODES "Sour cream "

123

NFCSCODES "Imitation and soy milk"

113

NFCSCODES "Non-dairy and dairy cream substitutes"

1220010	1221020	1222000	1222020	1222030
1221010	1221025	1222010	1222025	1222040

NFCSCODES "Dairy cream substitutes powdered"

1221040	1221041

NFCSCODES "Milk based meal replacements"

116

NFCSCODES "Milk dry and powdered mixtures"

118

NFCSCODES "Frostings and confections"

5440820	9110102	9110301	9110420
5440825	9110201	9110410	9110501

NFCSCODES "Poultry canned and ground"

2419854	2419856	2419864	2419866	2420600
2419855	2419857	2419865	2419867	2420700

NFCSCODES "Hard candy"
9174502 9177002

NFCSCODES "Jam and jellies, commercial"
914

NFCSCODES "Milk"
111

NFCSCODES "Sugar"
9110100 9110101

NFCSCODES "Sugar substitutes"
912

NFCSCODES "Sweet sauces and toppings"
913

NFCSCODES "Soy protein powders at"
4143000 4143010 4143021 4143031 4 144000
4143001

NFCSCODES "Soy protein drinks"
4143020 4144001 4144005 4144010 4145001

NFCSCODES "Soy protein bars"
4143501 414351 4146001

NFCSCODES "Soy based non dairy desserts"
4148000 4148001

NFCSCODES "Meat substitutes lunch meat"
4181020 4181040 -4181140 4181160 4181200

NFCSCODES "Veg Protein Bacon Bits"
4181025

NFCSCODES "Veg Protein based entree"
4181060 4181120 4181185 4181260 4181290
4181061 4181180

NFCSCODES "Veg Protein based sandwich"
4181190 4181240 4181245 4181280 419

NFCSCODES "Vegetarian bouillon"
4181300

NFCSCODES "Non-alcoholic beverages"
924 927 929

NFCSCODES " Gelatin beverages and meal supplements"
284

NFCSCODES "Fruit drinks"
925

NFCSCODES "Vegetable beverages"

73 10501	743	7513200	7513201	7520070

NFCSCODES "Gelatins and puddings"

132	6340299	6340300	63403 10	915

NFCSCODES "Candy soft"

9170001	9170505	9171309	9172611	9173410
9170050	9170506	9171500	9172613	9173420
9170101	9170507	9171510	9172615	9173901
9170301	9170520	9171511	9172641	9173960
9170302	9170521	9171520	9172642	9174501
9170303	9170530	9171530	9172701	9174504
9170304	9170540	9171611	9172800	9174510
9170306	9170541	9171800	9173100	9174602
9170307	9170600	9171805	9173101	9174610
9170320	9170610	9171810	9173106	9174615
9170330	9170700	9171820	9173110	9175000
9170335	9170701	9172100	9173115	9176000
9170340	9170801	9172300	9173200	9176010
9170350	9170803	9172301	9173300	9176050
9170501	9170900	9172302	9173320	9177000
9170502	9171303	9172305	9173400	9177003
9170503	9171304	9172600	9173405	9177005
9170504	9171305			

NFCSCODES "Quick breads"
52

NFCSCODES "All pasta"

561	5814	58302	58305
5813	58301	58304	583068

Menhaden Oil: Food Categories and Levels of Use
(GRAS Self-Determination March 1, 1999)

Category of Food	Maximum Level of Use In Food As Served
Previously Approved Uses:	
Cookies, crackers (1)	5.0%
Breads and rolls (1)	1.0%
*Pies (1)	3.0%
*Cakes (1)	4.0%
Cereals (4)	4.0%
Cheese products (5)	5.0%
Condiments (8)	5.0%
Elgg products (11)	5.0%
*Fats and oils (12)	12.0%
*Fish products (13)	5.0%
Frozen dairy desserts (20)	5.0%
Gravies and sauces (24)	5.0%
*'Meat products (29)	5.0%
Yogurt (3 1)	4.0%
Nut products (32)	5.0%
Snack foods (37)	5.0%
Soups and soup mixes (40)	3.0%
New Uses:	
Quick breads (1)	4.0%
Non-alcoholic beverages (3)	0.5%
Chewing gum (6)	3.0%
Confections and frostings (9)	5.0%
Dairy product analogs (10)	5.0%
Nondairy milk (10)	1.0%
Gelatins and puddings (22)	1.0%
Pasta (23)	2.0%
Hard candy (25)	10.0%
Jams and jellies (28)	7.0%
Gelatin drinks and meal supplements (29)	10.0%
Flavored milk and milk drinks (3 1)	0.5%
Milk products (3 1)	5.0%
Milk based meal replacements (3 1)	1.0%
Milk dry and powdered mixtures (3 1)	3.0%
Plant protein products (33)	5.0%
Poultry products (34)	3.0%
Processed fruit drinks (35)	1.0%
Processed vegetable drinks (36)	1.0%
Soft candy (3 8)	4.0%
White granulated sugar (4 1)	4.0%
Sugar substitutes (42)	10.0%
Sweet sauces, toppings and syrups (43)	5.0%

* Food categories with amended maximum levels of use.

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